

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal Department or agency;

(b) have not within a 3-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) are not presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) have not within a 3-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

The inability of a person to provide the certification required above will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the Department of Health and Human Services (HHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

The prospective primary participant agrees that by submitting this proposal, it will include the clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transaction" provided below without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions (To Be Supplied to Lower Tier Participants)

By signing and submitting this lower tier proposal, the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

(b) where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal.

The prospective lower tier participant further agrees by submitting this proposal that it will include this clause entitled "certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions. "without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Certification Regarding Environmental Tobacco Smoke

Public Law 103-227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees certify accordingly.

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Centers for Disease Control and Prevention

[Announcement 560]

National Institute for Occupational Safety and Health; Implementation of Strategies for the Prevention of Occupational Transmission of Blood-Borne Pathogens

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for a cooperative agreement program for implementation and evaluation of strategies, including compliance with infection control recommendations, to prevent occupational transmission of blood-borne pathogens, including the human immunodeficiency virus (HIV) and related infections (e.g., Mycobacterium tuberculosis).

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering a copy of Healthy People 2000 see the section Where to Obtain Additional Information.)

Authority

The legislative authority for this program is contained in Sections 20(a)(1) and 22(e)(7) of the Occupational Safety and Health Act (29 U.S.C. Sections 669(a)(1) and 671(e)(7)).

Smoke-Free Workplace

The PHS strongly encourages all recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, non-profit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, health-care institutions, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

Availability of Funds

Approximately \$1,300,000 is available in FY 1995 to fund approximately 4 to 6 awards. It is expected that the average award will be \$271,000, ranging from \$216,000 to \$325,000. It is expected that the awards will begin on or about September 30, 1995, and will be made for a 12-month budget period within a project period of up to 3 years. (At least one behavioral science project will be included.) Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The purpose of this cooperative agreement program is to utilize the special resources of the extramural community to assist in the implementation and evaluation of strategies for the prevention of occupational transmission of blood-borne and related pathogens among certain workers.

The control technology component will evaluate the effectiveness of engineering control or personal protective equipment in preventing occupational exposure to blood. Evaluation parameters include efficacy of exposure prevention, prevention effectiveness including cost analysis, and impact on patient care. A discussion of methodologies for conducting prevention effectiveness is presented in A Framework for Assessing the Effectiveness of Disease and Injury Prevention (CDC, Morbidity and Mortality Weekly Report, March 27, 1992, Volume 41, Number RR-3, pages 5-11). (For ordering a copy of A Framework for Assessing the Effectiveness of Disease and Injury Prevention, see the Section Where to Obtain Additional Information.)

The behavioral evaluation component of this cooperative agreement will assess the efficacy of one or more specific intervention(s) to affect organizational, social and/or individual health-care workers' behavior(s) to improve compliance with CDC recommendations and to generate data upon which to base recommendations for practical methods of increasing worker compliance.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for conducting activities under B. (CDC Activities).

A. Recipient Activities

From among the following activities, applicants should address the general activities and those areas that are within the interests and strengths of their organizations:

1. General

a. Develop communication models for informing management and labor of the nature of the work hazards and for modifying attitudes and behavior.

b. Publish results of research in appropriate scientific literature.

2. Blood-Borne Pathogen Control Technology

a. Develop a plan to evaluate the efficacy and effectiveness of specific types of control technologies including devices/personal protective equipment for prevention of blood exposures in a health-care workplace. This plan should include: (1) collection and analysis of data on needlestick/sharps injuries; (2) identification of new technologies to reduce needlestick/sharps injuries; (3) analysis of the impact of implementation of new technologies on the incidence, epidemiology and cost of needlestick injuries/blood exposures; and (4) determination of the relationships between exposures and devices/equipment. The plan may also include: (1) development of device/personal protective equipment selection and evaluation criteria; (2) evaluation of the decision analysis process for purchasing anti-needlestick devices and evaluation of cost-effectiveness; (3) collection and analysis of data regarding positive and negative aspects of user acceptance for devices; (4) evaluation of impact of placement/and use of devices/equipment such as in patient rooms and emergency vehicles; and (5) impact of user/worker involvement (e.g., focus groups) in the selection and evaluation of devices. The plan should include a detailed evaluation methodology.

b. Develop and maintain a data management system for the study.

3. Behavioral

a. Develop, implement, and evaluate a plan that assesses one or more specific interventions to improve workers' compliance with specific infection control (IC) recommendations (e.g., hand washing, use of personal protective equipment, appropriate sharps disposal).

b. Develop a plan to evaluate one or more specific interventions by: (1) implementing the intervention(s) in a health-care work place; (2) quantifying its impact on an appropriate measurable outcome related to compliance with IC recommendations; and (3) using the

data to propose practical recommendations to increase workers' compliance with IC recommendations. The plan should include a detailed description of the evaluation methodology, including describing potential confounders/bias that might affect the data and addressing methods to account for these confounders/bias.

c. Develop and maintain a data management system for the study.

B. CDC Activities

1. Provide consultation and technical assistance in the conduct of the intervention evaluation, including input in the development of intervention design and review of raw and summary data.

2. Provide assistance on analysis, dissemination, presentation and publication of the data.

3. Provide scientific information related to the proposed research topics.

4. Meet periodically with recipient(s) to discuss progress, exchange information, and seek means of resolving problems which have arisen.

5. Assist in predicting hazards that may be associated with new technologies and new occupations and characterize changes that are occurring in health care settings and occupational safety and health.

6. Assist in determining the efficacy and effectiveness of intervention and in measuring the impact of prevention.

Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

1. Understanding of Purpose and Objectives (15%)

Responsiveness to the objective of the cooperative agreement including: (a) applicants understanding of the objective of the proposed cooperative agreement, (b) relevance of the proposal to the objective, and (c) willingness to cooperate with CDC in the design, implementation and analysis of the project. The extent to which the applicant demonstrates knowledge and understanding of health-care settings and interventions described in this cooperative agreement.

In addition, applications targeting the behavioral component should specifically address: The extent to which the applicant demonstrates knowledge and understanding of health care settings and work behaviors/practices which influence compliance with infection control recommendations and need to develop specific practical interventions that will influence

workers compliance with recommended infection control practices.

2. Study Design (40%)

Steps proposed in planning, implementing, and evaluating a project. The quality of the plans to coordinate and conduct the project, including a description of techniques for data collection, management, and analysis and a schedule for accomplishing the program activities, including time frames. The quality and feasibility of the proposed program activities for achieving the objectives, including the applicant's ability to conduct control technology or behavioral intervention studies with sufficient numbers to draw meaningful conclusions in a reasonable time period. The extent to which the intervention is specific and practical to implement in a hospital or other appropriate clinical setting.

If the outcome variable could be affected by confounding variables or biases, the extent to which the proposal addressed these confounding variables or biases to ensure that they do not call into question the results of the intervention assessment. Extent to which the outcome variable(s) chosen represents potentially important risks for large numbers of HCWs and/or patients in U.S. hospitals.

In addition, applications targeting the behavioral component should specifically address: The extent to which the appropriate methodology is proposed so that the targeted compliance behavior(s) (outcome variable) measured is reliably quantifiable.

The extent to which the proposed evaluation system will document program process, efficacy, effectiveness, impact, and outcome, and, if applicable, measure surveillance system sensitivity, timeliness, representativeness, predictive values, and ability to detect the impact of specific intervention on morbidity, mortality, severity, disability, and cost of related diseases, injuries and prevention interventions. The extent to which a feasible plan for reporting evaluation results and using evaluation information for programmatic decisions is included.

3. Program Personnel (25%)

Qualifications and time allocation of the professional staff to be assigned to a project and applicant's ability to provide the knowledgeable staff required to perform the applicant's responsibilities in this project, and to describe the approach to be used in carrying out those responsibilities. How the study will be administered, including the size, qualifications,

duties, responsibilities, and time allocation, of the proposed staff. A statement of the applicant's demonstrated capabilities and experience in conducting such a project.

4. Facilities and Resources (20%)

The adequacy of the applicants facilities, equipment, and other resources available for performance of a project.

5. Budget and Justification (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of the funds.

Executive Order 12372 Review

This program is not subject to review by Executive Order 12372.

Public Health System Reporting Requirements

This program is not subject to the Public Health System reporting Requirements.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number is 93.262.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by this cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicants must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Application Submission and Deadline

The original and two copies of the application PHS form 5161-1 (revised 7/92, OMB Number 0937-0189) must be submitted to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Mailstop E-13, Atlanta, GA 30305 on or before July 17, 1995.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.)

2. Late Applications: Applications which do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, telephone number and will need to refer to Announcement 560. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6521. Programmatic technical assistance may be obtained from Linda S. Martin, Ph.D., National Institute for Occupational Safety and Health, HIV Activity, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Mailstop F-40, Atlanta, GA 30333, telephone (404) 639-2377.

Please refer to Announcement Number 560, when requesting information and submitting an application.

Copies of A Framework for Assessing the Effectiveness of Disease and Injury

Prevention (CDC, Morbidity and Mortality Weekly Report, March 27, 1992, Volume 41, Number RR-3, pages 5-11) may be obtained by calling (404) 488-4334.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: June 5, 1995.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

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[Announcement 575]

National Institute for Occupational Safety and Health; Evaluation of the Effectiveness of Medical Management and Rehabilitation Programs for Work-Related Musculoskeletal Disorders

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for cooperative agreements to provide assistance for the development, implementation, and evaluation of demonstration projects that will determine the overall effectiveness of medical management and rehabilitation programs for individuals with work-related musculoskeletal disorders.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering a copy of Healthy People 2000, see the Section Where to Obtain Additional Information.)

Authority

The legislative authority for this program is authorized under Sections 20(a) and 22(e)(7) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a) and 671(e)(7)) and Section 501(a) of the Federal Mine Safety and Health Act (30 U.S.C. 951).

Smoke-Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free

workplace and promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, non-profit and for-profit organizations. Thus, universities, colleges, research institutions, hospitals, and other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

Availability of Funds

Approximately \$225,000 is available in FY 1995 to fund approximately 1 to 2 awards. It is expected the award(s) will begin on or about September 30, 1995, and will be made for a 12-month budget period within a project period of 3 to 5 years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The purpose of the demonstration projects is to assess the effectiveness of medical management programs regarding rehabilitation and return-to-work of employees with work-related musculoskeletal disorders. Through the development and application of objective evaluation criteria, the project will provide a basis with which to compare the success rate of various medical management, rehabilitation and return-to-work programs. In addition, the demonstrations will provide additional data on the types of programs available; components of the programs; elements necessary for successful programs; the success rates of programs for returning populations to work and possible explanations; the influence programs have in convincing employers to change activities in jobs where the injury was noted; and the direct and indirect costs of successful medical management, rehabilitation, and return-to-work programs.

This program may build on an existing program or provide assistance in initiating a new program. Personnel for the demonstration projects will include researchers from many disciplines such as ergonomics,

epidemiology, occupational medicine, physical and occupational therapy and physical and rehabilitation medicine, nursing, health education, and economics. Additionally, this program will report and disseminate findings, relevant health and safety education and training information to State health officials, health-care providers, workers, management, unions, and employers. It is envisioned that new research methods and techniques will be developed that improve the success of rehabilitation and return-to-work programs for work-related musculoskeletal disorders.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC/NIOSH will be responsible for the activities listed under B. (CDC/NIOSH Activities).

A. Recipient Activities

1. Develop and conduct a demonstration project for the evaluation of medical management, rehabilitation and return-to-work programs targeted at work-related musculoskeletal disorders.

2. Develop objective criteria for determination of "successful" medical management, rehabilitative, and return-to-work programs for work-related musculoskeletal disorders. (Issues to consider include assessment of the level of exposure prior to the injury and the type of job to which the individual returns, and how the job where the injury was noted was changed to reduce the risk of injury to workers.)

3. Identify existing medical management, rehabilitative and return-to-work programs to validate criteria and facilitate implementation of the demonstration project.

4. Develop a protocol that reviews the pertinent literature on program evaluation, describes the project methodology, the data to be collected and the proposed analysis of the data. Present the protocol to a panel of peer reviewers and revise the protocol as required for final approval.

5. Conduct data collection, management and analysis.

6. Prepare a final report summarizing the study methodology, results obtained, and conclusions reached, including recommendations regarding critical elements of effective medical management, rehabilitation and return-to-work programs for work-related musculoskeletal disorders.

7. Report research results to the scientific community via presentations at professional conferences and articles